Complete Summary

GUIDELINE TITLE

VHA/DoD clinical practice guideline for the management of adults with gastroesophageal reflux disease in primary care practice.

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for management of adults with gastroesophageal reflux disease in primary care practice. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar 12. 65 p. [255 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Gastroesophageal reflux disease (GERD)

GUI DELI NE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Gastroenterology Internal Medicine

INTENDED USERS

Advanced Practice Nurses Dietitians Health Care Providers Nurses Pharmacists Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To present options for the initial and long-term management of gastroesophageal reflux disease (GERD) from a primary care perspective
- To serve as a tool to aid primary care practitioners in making informed decisions about the diagnosis and pharmacologic treatment of GERD

TARGET POPULATION

Any person who is eligible for care in the Veterans Affairs or Department of Defense health care delivery system with suspected or confirmed gastroesophageal reflux disease (GERD)

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation and Diagnosis

- 1. Patient history
- 2. Physical examination
- 3. Laboratory tests (hemoglobin and hematocrit)
- 4. Further diagnostic tests
 - Endoscopy
 - Proton pump inhibitors (PPI) trial
 - Ambulatory pH monitoring
 - Barium esophagraphy
 - Provocative tests
 - Esophageal manometry

Treatment/Management

- 1. Initial treatment
- 2. Maintenance therapy
- 3. Step-up, step-down approach

Pharmacotherapeutic Agents

1. Antacids (with or without alginate)

- 2. Histamine H₂-receptor antagonists
 - Cimetidine
 - Famotidine
 - Nizatidine
 - Ranitidine
- 3. Proton pump inhibitors
 - Lansoprazole
 - Esomeprazole
 - Omeprazole
 - Pantoprazole
 - Rabeprazole

Nonpharmacological Treatment

- 1. Surgery (e.g., open or laparoscopic Nissen fundoplication)
- 2. Lifestyle changes
- 3. Dietary changes

Interventions Considered but Not Recommended

Metoclopramide, cisapride

MAJOR OUTCOMES CONSIDERED

- Symptomatic relief
- Relapse rate
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Updates of the present guideline relied primarily on two evidence-based publications on the diagnosis and management of gastroesophageal reflux disease (GERD), one developed by the American College of Gastroenterology and revised in June 1999, and the other prepared by an international panel of experts participating in the Genval Workshop and updated (with focus on primary care practice) in 2001.

Literature searches were performed to obtain updated, general information on the management of GERD and to obtain problem-directed evidence to support decision points and treatment pathways. Electronic searches were performed on all Evidence Based Medicine reviews available on OVID (included the Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effectiveness, and Cochrane Controlled Trials Register) and the National Library of Medicine's (NLM's) MEDLINE/PubMed database (1966 to May

2002). Preference was given to meta-analyses, systematic reviews, and randomized controlled trials. The Clinical Queries service of PubMed was used for focused searches for well-designed (e.g., double-blind or placebo-controlled) trials on therapy, diagnosis, or prognosis, usually with emphasis on specificity of searches. Relevant articles were also obtained from reference lists of retrieved articles.

In an attempt to find other up-to-date evidence-based clinical practice guidelines on medical management of GERD, the Web sites of the Agency for Healthcare Research and Quality (http://www.ahrq.gov), the National Guideline Clearinghouse (http://www.guideline.gov), and the National Institute for Clinical Excellence (http://www.nice.org.uk) were searched using American or British spellings of the term gastroesophageal reflux. A search was also performed via the Centre for Evidence-Based Medicine, University Health Network, Mount Sinai Hospital Web site (http://www.cebm.utoronto.ca/index.htm) and the Evidence Based Medical Practice Directory of the Family Medicine Department at Laval University. Guidelines for dyspepsia were not considered to be specifically applicable to GERD, although there is some overlap between the two conditions.

The main terms and limits applied in the literature searches are provided in Appendix 1 of the original guideline document. A complete list of references used in the development of the treatment algorithm, annotations, supplements, and appendix tables starts on page 47 of the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

- I: Evidence obtained from at least one properly randomized controlled trial
- II-1: Evidence obtained from well-designed controlled trails without randomization
- II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
- III: Opinion of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees

Overall Quality

I (Good): High grade evidence (I or II-1) directly linked to health outcome

II (Fair): High grade evidence (I or II-1) linked to intermediate outcome; OR moderate grade evidence (II-2 or II-3) directly linked to health outcome

III (Poor): Level III evidence or no linkage of evidence to health outcome

IV Insufficient evidence

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, OR
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, OR
- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative impact on a frequent condition with a substantial burden of suffering, OR
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, OR
- An infrequent condition with a significant impact on the individual patient level

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles supporting diagnostic or therapeutic interventions were reviewed for relevance and graded according to a rating scheme based on the methods of the third U.S. Preventive Service Task Force. Ratings were based on the quality of evidence (QE), overall quality (OQ), net effect of the intervention, and grade of the strength of recommendation (SR). The SR depends on the OQ of evidence and on the magnitude of net benefit.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Whenever possible the Pharmacy Benefits Management Strategic Healthcare Group Medical Advisory Panel (PBM-MAP) and the Pharmacoeconomic Center (PEC) rely upon evidence-based, multidisciplinary, nationally recognized consensus statements for the basis of clinical practice guidelines. Relevant literature was reviewed and assessed with considerations given to the Veterans Affairs and Department of defense populations.

The original guidelines that were merged in the creation of this document were (1) The Pharmacologic Management of Gastroesophageal Reflux Disease (PBM-MAP Publication No. 98-0010, dated September 1998, last updated March 2000) and (2) a draft update (last modified 20 January 2001) of Improving the Clinical and Economic Outcomes of Gastroesophageal Reflux Disease (GERD) (PEC Update, Vol. 98, Issue 4).

To focus on primary care practice, one of the major changes made to this guideline was a redirection from mainly using evidence derived from a subset of patients with reflux esophagitis, in whom endoscopic response was emphasized, to preferring evidence applicable to a mixed population of patients with different types of gastroesophageal reflux disease (GERD), particularly patients with uninvestigated GERD, in whom symptomatic response has become more clinically relevant.

Since the last updates to the guidelines by PBM-MAP (March 2000) and the PEC (draft update, January 2001), much information has been learned about the epidemiology of GERD and effective therapeutic strategies. Major changes to the previous guidelines include the following:

- Nonerosive reflux disease (NERD) has become recognized as a distinct type of GERD.
- Lifestyle modifications are no longer considered to be primary treatment, but are instead adjunctive measures in the overall treatment strategy of GERD.
- The choices of histamine H₂ receptor antagonists (H₂RAs) and proton pump inhibitors (PPIs) have expanded with the Food and Drug Administration (FDA) approval of a number of new agents, while the choices of prokinetic agents have been reduced by the implementation of a limited access program for cisapride.
- Doubling the dose of H₂RAs has been demonstrated to produce marginal benefits.

 Recent federal contracting initiatives have resulted in reductions in the drug acquisition costs of rabeprazole and lansoprazole, making these agents more cost-effective in the treatment of severe GERD.

Another major part of updating this guideline consisted of completely reformatting the text to make it more consistent with recommendations on clinical algorithm development proposed by the Society for Medical Decision Making and the Agency for Healthcare Research and Quality (formerly, Agency for Health Care Policy and Research).

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Overall Quality of Evidence	Net E	Net Benefit of the Intervention			
	Substantial	Moderate	Small	Zero or Negative	
I	Α	В	С	D	
11	В	В	С	D	
Ш	С	С	С	D	
IV	I	I	I	D	

Key:

- A A strong recommendation that the intervention is always indicated and acceptable
- B A recommendation that the intervention may be useful/effective
- C A recommendation that the intervention may be considered
- D A recommendation that a procedure may be considered not useful/effective, or may be harmful
- I Insufficient evidence to recommend for or against -- the clinician will use clinical judgment

COST ANALYSIS

Most economic analyses, under a variety of conditions and assumptions, find the proton pump inhibitors (PPIs) to be more cost effective than H_2 receptor antagonists (H_2 RAs) as initial or maintenance therapy with or without endoscopy, even when comparing a PPI (rabeprazole) to a generic H_2 RA (ranitidine).

One study that may be relevant to the Veterans Administration (VA) showed that stepping down therapy from a PPI to H_2 RAs, prokinetics, or both with a trial of drug discontinuation was successful in the majority (58%) of 71 evaluated patients. No significant changes in health-related quality of life or disease severity were observed 6 months after implementing step-down management, and the step-down approach resulted in a total annual cost savings of \$15,069 for the cohort.

Another study, which considered government procurement costs, favored PPIs over H_2RAs in patients with esophagitis when the differences in drug acquisition costs were small or when patients experienced substantial impairment in quality of life.

Federal contracting initiatives have reduced the cost of proton pump inhibitors (PPIs) (rabeprazole or lansoprazole) therapy. For instance, at the current federal drug prices, the monthly cost of standard-dose rabeprazole is about \$5 more than that of standard-dose ranitidine (see Table 24 of the original guideline document for details of the cost analysis of antireflux agents).

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Drafts of the full guideline or only the treatment algorithm were sent to Department of Defense (DoD) and Veterans Administration (VA) gastroenterologists and members of the Pharmacy Benefits Management Strategic Healthcare Group (PBM) and Pharmacoeconomic Center (PEC) for comment and to identify pivotal decision points in treatment pathways. Prior to being finalized, the guideline was made available on the Web through the Office of Quality and Performance to obtain comments from the field.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each algorithm, the objectives and recommendations or annotations that accompany it, and the evidence supporting the recommendations are presented below. The quality of evidence (QE) grading (I-III); overall quality (Good, Fair, Poor or insufficient evidence, I-IV); and final grade of recommendations (SR) (A-D, I) are provided for specific statements. These grades, along with "net effect of the interventions" are defined at the end of the "Major Recommendations" field.

A. Adult with Symptoms of Gastroesophageal Reflux Disease

Objectives

- To define gastroesophageal reflux disease (GERD)
- To list the causal mechanisms of gastroesophageal reflux (GER)
- To provide epidemiologic and other background information on GERD

Annotation

Definition of GERD

There is a lack of consensus on the definition of GERD at least partly because there is no diagnostic gold standard and there is disagreement about how to determine when occasional heartburn becomes the disease due to GER. GERD can be defined as chronic symptoms or mucosal damage secondary to abnormal reflux of gastric contents into the esophagus. According to one study, the term GERD should be used to include all individuals who are exposed to the risk of physical complications from gastroesophageal reflux, or who experience clinically significant impairment of health related well being (quality of life) due to reflux related symptoms.

Causal Mechanisms of GER

- Transient relaxation of the lower esophageal sphincter
- Increased intra-abdominal pressure that overpowers a decrease in lower esophageal sphincter tone
- Impaired esophageal or gastric motility

In the majority of patients, GERD-related symptoms are caused by the abnormally prolonged exposure of the esophageal mucosa to acid and pepsin. In a minority of patients, normal levels of esophageal acid exposure may produce reflux symptoms.

Epidemiology

Possible complications of GERD and their respective prevalence or incidence rates are shown in the table below titled "Rate of Complications from GERD".

Table. Rate of Complications from GERD

Complication	Rate of Occurrence
Barrett's esophagus	10 to 15%
Esophageal stricture	4 to 20%
Esophageal ulceration	2 to 7%
Esophageal hemorrhage	<2%
Esophageal perforation	<0.2%
Esophageal perforation	<0.2%
Esophageal adenocarcinoma	
With Barrett's esophagus	0.5%/y
Without Barrett's esophagus	0.07%/y

The majority (up to 50 to 70%) of patients with frequent GERD symptoms in community or general practice have a macroscopically normal endoscopic examination (nonerosive reflux disease [NERD]). NERD may not simply be a mild form of GERD but may represent a distinct and heterogeneous subset of GERD in which increased esophageal sensitivity to acid may play a more prominent role in symptom production.

B. Perform Initial Evaluation

Objectives

To discuss the initial evaluation of a patient with GERD symptoms

Annotation

History

A detailed history should be obtained from all patients regarding

- Symptom description
- Exacerbating factors
- Measures taken to relieve symptoms
- Response to previous treatments

Symptom Description

The classic or typical symptoms of GERD are those of heartburn and/or acid regurgitation (see table below titled "Signs and Symptoms of GERD and Potential Complications").

Table. Signs and Symptoms of GERD and Potential Complications

Common symptoms	Heartburn Regurgitation Dysphagia (difficulty swallowing)
Unusual symptoms	Hypersalivation (waterbrash) Nausea Odynophagia (painful swallowing)
Extraesophageal manifestations	Asthma Chest pain, noncardiac Chronic cough Dental disease Globus sensation Hoarseness Laryngitis Respiratory symptoms
Signs and symptoms of potential complications	Abdominal mass Anemia Hemorrhage Weight loss
Alarm symptoms (suggestive of cancer)	Dysphagia Odynophagia Weight loss Hematemesis Black or bloody stools Chest pain Choking

A predominance of heartburn, regurgitation, or both, which often occur after meals (particularly large or fatty meals) are highly specific for GERD.

Exacerbating Factors

Reflux symptoms most often occur after meals, while a small proportion of patients experience nocturnal reflux symptoms. Although dietary and lifestyle factors have been implicated in the pathogenesis of GERD, evidence of their role has been poorly documented. In some individuals, however, ingestion of certain foods and specific lifestyle factors may precipitate or worsen symptoms of GERD. (Also see section H titled "Consider Adjunctive Nonpharmacologic Measures".) Factors that may exacerbate or contribute to symptoms include the following:

- Gastric distension (e.g., voluminous meals)
- Supine position, particularly the right lateral decubitus position
- Bending over
- Certain foods or beverages (e.g., alcohol, caffeinated beverages, carbonated beverages, peppermint/spearmint, chocolate, citrus, high-fat foods, milk, onions, garlic, spicy foods, tomato juices)
- Excessive physical activity (e.g., running)

Risk factors associated with GERD include the following

- Psychological stress
- Psychiatric disease
- Alcohol
- Smoking
- Obesity (body mass index >30 kg/m²)
- An immediate family history of heartburn or gastroesophageal disease
- Use of nonsteroidal anti-inflammatory drugs

A medication history should be obtained to identify agents that may contribute to symptoms of GERD (see table in the original guideline document titled "Medications Contributing to Symptoms of GERD").

Factors possibly protective against GERD include chronic gastritis and Helicobacter pylori infection.

Measures Taken to Relieve Symptoms

Many patients who present with GERD have mild or infrequent symptoms and do not seek medical intervention unless they have failed a trial of nonprescription drug therapy, such as antacids or half-dose H₂ receptor antagonists (H₂RAs), or have not obtained adequate relief after discontinuing foods, beverages, or medications that exacerbate their symptoms.

Response to Previous Treatments

A history of partial or complete relief of reflux symptoms with antacids or half-dose H₂RAs suggests an acid-peptic disorder and may be helpful in making a clinical diagnosis.

Physical Exam

The provider should search for any signs of extraesophageal disease, complications of advanced disease, or diseases that may present with GERD symptoms (e.g., gastric or esophageal carcinoma).

Laboratory Tests

No routine laboratory tests are required. However, hemoglobin and hematocrit would be helpful to detect anemia, particularly in patients with hematemesis, other signs of gastrointestinal bleeding, or severe, unremitting symptoms. Further diagnostic work-up is warranted in patients presenting with atypical symptoms or when manifestations of more severe or complicated disease are apparent. Routine testing for H. pylori (with subsequent eradication of the organism if present) is of little benefit in patients with GERD.

C. Make a Clinical Diagnosis

Objective

To discuss the clinical diagnosis of GERD

Annotation

Base Diagnosis on Symptoms and Response to Previous Antireflux Therapy

There is no gold standard for the diagnosis of GERD, and no standardized, symptom-based, diagnostic algorithm for making a diagnosis of GERD.

Since there is a lack of physical, physiologic, or biochemical markers for GERD, the diagnosis of GERD is usually based on symptoms and associated risk factors, although many symptoms of GERD are nonspecific.

The presence of heartburn, acid regurgitation, and relief of heartburn with antacid or acid suppressive agents (a response that suggests an acid-peptic disorder) reinforces a diagnosis of GERD.

It is important to remember that the intensity and frequency of reflux symptoms are poor predictors of the presence or severity of esophagitis. GERD may be present without the concomitant findings of mucosal breaks (erosions) in the esophagus (NERD), just as tissue damage may be identified in the absence of typical symptoms of heartburn or regurgitation.

Conditions to Exclude (Not Covered by These Guidelines)

There can be considerable overlap in symptoms between functional dyspepsia and GERD, particularly NERD, depending on the definitions used for either disorder. Dent et al. recommend that patients with heartburn should be distinguished from those with dyspepsia as defined by the Rome criteria, which excludes heartburn from the definition of dyspepsia. Patients experiencing dyspepsia rather than heartburn should be managed according

to a different decision pathway, recognizing that true dyspepsia may be caused by GER.

D. Refer for Further Diagnostic Testing

Objective

To discuss the indications for further diagnostic testing

Annotation

Empiric therapy for GERD is reasonable without diagnostic testing. Patients who present with typical symptoms of GERD in the absence of longstanding, frequently recurring, progressive, or alarm symptoms or complicated disease may be started on empiric treatment and rarely need a confirmatory diagnostic test since symptom resolution is the primary clinical end point.

The recommendations of the Practice Parameters Committee of the American College of Gastroenterology (PPCACG) for further diagnostic testing are shown in the table below titled "Indications for Further Diagnostic Testing (PPCACG)".

Table. Indications for Further Diagnostic Testing (PPCACG)

- Lack of response to therapy
- Need for continuous chronic therapy
- Chronic symptoms in a patient at risk for Barrett's esophagus*
- Alarm symptoms suggesting complicated GERD:
 - Bleeding
 - Chest pain
 - Choking (acid causing coughing, shortness of breath, or hoarseness)
 - Dysphagia
 - Weight loss

Patients with alarm symptoms may receive initial therapy with a proton pump inhibitor (PPI) while they are awaiting further evaluation. The presence of alarm symptoms, however, requires immediate referral for diagnostic testing.

Repeated endoscopy is usually not indicated, as sustained symptom resolution reasonably reflects healing of esophagitis and is the accepted primary clinical end point. The absence of heartburn has a high predictive value (91.4%) for endoscopic remission; however, the presence of heartburn has a low predictive value (26.8%) for relapse of esophagitis. Symptom response (control or complete relief of heartburn) may be more frequently associated with healing of esophagitis after treatment with a PPI than with an

^{*}Endoscopy to screen for Barrett's esophagus is recommended in patients with a long duration of GERD symptoms (e.g., >5 years), particularly white males who are 50 or more years of age.

 H_2RA . Among patients with persistent heartburn, a smaller proportion of PPI-treated patients than H_2RA -treated patients still have unhealed erosions.

GERD that is refractory to drug therapy is rare. Nonresponders to adequate trials of drug therapy, particularly PPI therapy, should have their symptoms reassessed, undergo endoscopy if it was not previously done, and be considered for additional diagnostic work-up. For further discussion on indications for repeat endoscopy and information on specific diagnostic tests for GERD, see Diagnostic Tests on page 33 of the original guideline document.

Intervention	Reference(s)	QE	00	SR
Immediate referral for	DeVault & Castell, 1999; "An	Ш;	Ш	С
diagnostic testing if alarm	evidence-based appraisal," 1999	Ш		
symptoms are present				
Repeated endoscopy is	"The role of endoscopy," 1999;	Ш;	П	С
usually not indicated	Vigneri et al., 1995; Carlsson et al.,	l; l;		
	1997; Richter & Bochenek, 2000;	l; I		
	Vakil et al., 2001			
Reassessment and further	DeVault & Castell, 1999; "An	Ш;	Ш	С
diagnostic testing in	evidence-based appraisal," 1999;	Ш;		
nonresponders	"The role of endoscopy," 1999	Ш		

E. Start Standard-dose PPI; if Symptoms Persist, Refer for Further Diagnostic Testing or Consultation

Objective

To discuss the management of patients with possible extraesophageal GERD

Annotation

Effective treatment for extraesophageal GERD is not standardized. Well-designed studies comparing different pharmacologic treatments of extraesophageal GERD are lacking. The literature search found no well-designed trials comparing H_2RAs with PPIs or standard doses with higher doses of PPIs in the treatment of extraesophageal GERD. This guideline recommends considering empiric, standard-dose PPI as initial therapy.

For initial management of extraesophageal symptoms of GERD, expert consensus opinion favors empiric therapy with double-dose PPI (in two divided doses for at least 2 to 3 months) over invasive diagnostic testing because (1) ambulatory pH testing lacks diagnostic accuracy in patients with extraesophageal GERD, (2) a diagnostic trial of PPI is at least as sensitive as pH testing for diagnosing GERD, and (3) ambulatory pH testing or qualified personnel to interpret the test results may not be locally available. This guideline suggests that the need for double-dose PPI should be based on patient response to standard-dose PPI, confirmation of a presumptive diagnosis of extraesophageal GERD, and any diagnostic findings.

Some patients may require higher doses and longer duration of acid suppressive therapy for adequate control of extraesophageal symptoms, and

response to treatment may partly depend on the type of extraesophageal GERD.

Adjunctive therapy with antacids and postural lifestyle modifications may be considered but cannot be recommended for asthma or other types of extraesophageal GERD symptoms because of the lack of well-designed trials, inconsistent effects on asthma symptoms, and lack of improvement in pulmonary function tests.

Patients with persistent symptoms of GERD and extraesophageal symptoms deserve further diagnostic testing (also see Annotation D above) or consultation. Diagnostic tests in addition to those performed for GERD may be required.

Intervention	Reference(s)	QE	OQ	SR
Trial of standard-dose PPI if a patient has	GERD guideline expert	Ш	Ш	С
' 0	opinion			
symptoms of GERD				
Prefer empiric therapy with double-dose	Johnson, 2000; Hogan &	Ш;	ш	C
PPI over invasive diagnostic testing for	Shaker, 2001	Ш		
initial management of possible				
extraesophageal symptoms of GERD				
Antacids and postural lifestyle	Gibson, Henry, &	I; I	H	C
modifications for extraesophageal GERD	Coughlan, 2002; Kjellen,			
symptoms	Tibbling, & Wranne,			
	1981			
Patients with persistent symptoms of	DeVault & Castell, 1999	Ш	ш	C
GERD and extraesophageal symptoms				
should undergo further diagnostic testing				

F. Does Patient Have Long Duration of Symptoms?

Objective

To discuss the standard of practice and outcome evidence related to screening for Barrett's esophagus

Annotation

Endoscopy to screen for Barrett's esophagus is recommended in patients with a long duration of GERD symptoms (e.g., >5 years), particularly white males who are 50 or more years of age. Furthermore, the duration of therapy may need to be included in calculating when to screen for Barrett's esophagus because acid suppression may not alter progression, and symptoms may not predict the presence of Barrett's esophagus.

The use of endoscopy to detect or screen for Barrett's esophagus and at what point a patient should be evaluated are controversial issues. There is a lack of evidence that screening prevents death from esophageal adenocarcinoma. The associated time, effort, and costs to perform wide-scale screening of patients at risk would be prohibitive. In addition, screening for Barrett's

esophagus would miss up to 40% of patients with Barrett's esophagus who have no symptoms of GERD.

Decisions to screen for Barrett's esophagus should be made with the understanding that there is a lack of evidence that these recommendations favorably affect patient survival or quality of life.

	T			
Intervention	Reference(s)	QE	OQ	SR
	1 '	Ш	Ш	С
	1998			
(e.g., >5 years), particularly white males who are				
50 or more years of age				
	Lack of	١٧	IV	
esophageal adenocarcinoma	evidence			

G. Begin Empiric, Initial Therapy

Objective

To discuss reasons for stratified therapy based on results of early endoscopy vs. empiric treatment with delayed endoscopy in patients without alarm symptoms

Annotation

There is a lack of data on the relative value of performing pre-treatment endoscopy upon the initial diagnosis versus starting empiric therapy, and the choice of strategy is controversial. There are reasons favoring either approach (See table in the original guideline document titled "Reasons for Early Endoscopy vs. Empiric Treatment"). (Note: The reasons for early endoscopy given in this guideline in the context of timing of endoscopy are different from the indications for endoscopy. Indications for endoscopy are discussed in Annotation D and under the section titled "Diagnostic Tests.")

The Second Canadian Consensus Conference on the Management of GERD proposed a once-in-a-lifetime endoscopy mainly to detect Barrett's esophagus or esophageal cancer rather than erosive esophagitis. However, the risk of developing esophageal adenocarcinoma associated with Barrett's esophagus is very low in nonselected patients in primary care. Experts generally agree that detection of Barrett's esophagus should not be the primary reason for endoscopy. (Also see Annotation F.)

At some facilities, early endoscopy would be chosen, but for the purposes of this guideline--in the absence of evidence to favor early, invasive diagnostic testing--empiric therapy is the preferred option.

Intervention	Reference(s)	QEOQSR
Empiric treatment in patients without	GERD guideline expert	III III C
alarm symptoms	opinion	

H. Consider Adjunctive Nonpharmacologic Measures

Objective

To discuss nonpharmacologic measures as adjuncts to acid-suppressive therapy

Annotation

Although certain dietary and lifestyle factors may precipitate or exacerbate symptoms of GERD, most nonpharmacologic measures are not considered to be generally recommendable as sole therapy of GERD (See table in the original guideline document titled "Nonpharmacologic Measures to Reduce GERD Symptoms").

Dietary or lifestyle modification should be considered an adjunctive measure and not a distinct step in the treatment of GERD. Practitioners should consider the potential for positive and negative consequences of lifestyle modifications on the patient's quality of life, and the possibility that any beneficial effects may be small compared with the acid suppressive effects of PPIs and H₂RAs.

Intervention	Reference(s)	QE	\cap	SR
	· · · · ·		_	C
voluminous meals, lose weight, quit	2000		'''	
smoking, avoid excessive physical activity,	F * * *			
and sleep lying on the left side of the body				
(based on scientific evidence and				
pathophysiologic mechanism)				
Check individual patients for potentially	"An evidence-based	111;	Ш	С
important exposure to dietary and lifestyle	appraisal," 1999;	Ш;		
factors	Meining & Classen,	Ш		
	2000; DeVault &			
	Castell, 1999			
Nonpharmacologic measures are of		Ш	Ш	C
minimal benefit or not sufficiently	appraisal," 1999			
effective				
Nonpharmacologic measures as sole				
therapy:				
Avoid alcoholic beverages	Feldman & Barnett,	Ш	IV	l l
	1995			
Avoid carbonated beverages	Feldman & Barnett,	Ш	ΙV	l l
	1995			
Avoid chocolate	Murphy & Castell, 1988		П	С
Avoid citrus products and juices		Ш	IV	l l
	1995			
Avoid excessive physical activity	Lack of studies in	IV	ΙV	l l
	patients with GERD			
Avoid raw onions	Allen et al., 1990	11-3	Ш	С
Avoid voluminous meals	Holloway et al., 1985	I	Ш	С
Elevate the head of the bed	Stanciu & Bennett,	1; 1;	П	C

Intervention	Reference(s)	QE	OQ	SR
	1977; Harvey et al., 1987; Johnson & DeMeester, 1981	11-3		
Favor decaffeinated coffee	Pehl et al., "The effect of decaffeination," 1997		11	С
Lose weight (if obese)	Fraser-Moodie et al., 1999; Kjellin et al., 1996; Mathus-Vliegen & Tytgat, 1996	- 3; ; 	II	D
Quit smoking	Pehl et al., "Effect of smoking," 1997; Kadakia et al., 1995; Waring et al., 1989	- 2; - 3; -3	11	С
Reduce coffee intake	Feldman & Barnett, 1995	Ш	IV	I
Reduce fat intake	Penagini, Mangano, & Bianchi, 1998; Becker et al., 1989	I; I	П	D
Sleep in the left lateral decubitus position	Shay et al., 1996	11-3	Ш	С
Nonpharmacologic measures as an adjunct to acid-suppressive agents				
Elevate the head of the bed	Harvey et al., 1987	l	Ш	C

I. (Start) Standard-Dose PPI X 4 to 8 wk (In Patients who Have Had an Incomplete Response to a Previous Trial of H_2RA)

Objective

To explain the rationale for selecting standard-dose PPI over extending the treatment duration with either the same or higher dose of H_2RA in patients who have had an incomplete response to a previous trial of H_2RA

Annotation

Considering the consistent documentation that limited benefit is gained from extending the duration of H_2RA therapy at the same or higher doses, and the superiority of PPIs over double-dose H_2RAs , this guideline considers standard-dose PPI therapy to be the appropriate choice in patients who have had an incomplete response to a previous trial of either nonprescription or prescription H_2RA therapy.

Intervention	Reference(s)	QE	00	SR
If there is an incomplete	Hallerback et al., 1998; Kahrilas,	l; l;	I	C/D
response to initial H ₂ RA	Fennerty, & Joelsson, 1999; Pace,	l; l;		
therapy, extending the	Sangaletti, & Bianchi Porro, 1990;	l; l;		
duration of H ₂ RA therapy	Wesdrop, Dekker, & Festen, 1993;	l; I;		

Intervention	Reference(s)	QE	OQ	SR
at the same or higher	Porro et al., 1992; Simon et al., 1994;	l; l;		
dose produces limited	Quik et al., 1990; Roufail et al., 1992;	l; I		
benefit	Euler et al., 1993; Johnson et al.,			
	1989; Cloud & Offen, 1994; Tytgat,			
	Nicolai, & Reman, 1990			
Switch to a PPI if there is	Maton, Orlando, & Joelsson, 1999;	I; II-	П	В
an incomplete response	Richter et al., 1996; Lundell et al.,	2; I;		
to H₂RA therapy	1990; Porro et al., 1992	I		

J. Consider Options of H₂RA vs. PPI

Objective

To discuss issues to consider when choosing between H₂RAs and PPIs for empiric initial therapy

Annotation

In patients who have not previously received H_2 RAs or PPIs, there is insufficient evidence to support choosing one type of agent over the other as initial therapy of GERD. Expert opinion can provide reasonable justification for either a step-up or step-down treatment approach.

These guidelines suggest that the individual provider should decide the treatment approach in consultation with the patient. Reasons for not advocating one treatment approach over the other in patients who have not previously received H_2RAs or PPIs and for not stratifying treatment based on symptom severity are presented in the original guideline document.

For empiric initial treatment of GERD, there is a lack of evidence and consensus to support using one treatment approach over the other.

There is a lack of evidence to support the practice of stratifying empiric initial therapy based on intensity or frequency of symptoms.

Intervention	Reference(s)	QE	00	SR
The initial treatment	Bate et al., 1997; Armstrong et al.,	1; 1;	П	C
approach may be either	2001; Venables et al., 1997; Kaplan-	I; II-		
		2; I;		
first) or step-up therapy	1998; Wiklund et al., 1998; Howden et	I; I;		
(H ₂ RA first)	al., 2001; DeVault & Castell, 1999; "An	III;		
	evidence-based appraisal," 1999; Dent	Ш;		
	et al., 2001	Ш		
Initial treatment should	GERD guideline expert opinion	Ш	Ш	C
not be stratified based				
on severity of				
symptoms				

K. If Response to PPI Therapy is not Adequate, Consider Extending Treatment Duration (by 4 to 8 wk) at Same Dose or With Double-Dose PPI

Objective

To discuss the pharmacologic options for managing patients who do not adequately respond to initial therapy with standard-dose PPI

Annotation

The recommended duration of therapy for PPIs in the treatment of GERD is 4 to 8 weeks. An inadequate response to a course of standard-dose PPI may indicate longer treatment is needed, more severe disease, or incorrect diagnosis. Additional benefit may be obtained by extending treatment with either the same or double doses of PPI. In either case, the patient should be referred for further diagnostic testing (also see Annotation D above).

Intervention	Reference(s)	QE	OQ	SR
If there is an	Bate et al., 1990; Porro et al., 1992;	1; 1; 1;	ı	В
inadequate response to	Fass et al., 2000; Sandmark et al.,	1; 1; 1;		
a course of standard-	1988; Sontag et al., 1992; Mossner et	II-2;		
dose PPI, extend	al., 1995; Bate et al., 1993; Robinson	II-2;		
treatment with either	et al., 1993; Hetzel et al., 1988;	1; 1; 1;		
the same or double	Corinaldesi et al, 1995; Earnest et al.,	1; 1; 1;		
dose of PPI	1998; Mee & Rowley, 1996; Castell et	l I		
	al., 1996; van Rensburg et al., 1996;			
	Mulder, Dekker, & Gerretson, 1996			
The patient who does	DeVault & Castell, 1999; "An evidence-	Ш; Ш	Ш	C
not respond to a course	based appraisal," 1999			
of standard-dose PPI				
should be referred for				
further diagnostic				
testing				

L. Consider Options of Attempting to Step Down and Discontinue Therapy vs. Continuing Current Therapy

Objective

To discuss options for maintenance therapy

Annotation

GERD is a chronic relapsing-remitting disease, and NERD may also be characterized by periods of exacerbation and remission. Maintenance therapy constitutes both the cornerstone of GERD management and the main economic burden in the management of this often life-long disease. The goals of maintenance therapy are to keep symptoms under control, prevent relapse, and prevent progression of disease and complications. Failure to

treat relapse may put the patient at risk for complications of GERD and progressive deterioration of esophageal function.

If a patient has an adequate, sustained response to initial therapy, this guideline suggests two possible options for maintenance therapy:

- 1. Step-down management with attempted discontinuation of therapy (preferred); or
- 2. No-step management (i.e., continuation of the current medication regimen)

The optimal approach to maintenance therapy is unclear. The two choices suggested by this guideline have been more commonly evaluated in efficacy or economic studies. If relapse occurs, the choice of subsequent treatment approach also lacks consensus--to reinstitute continuous therapy, to reinstitute continuous therapy then step down, or to intermittently treat each relapse.

After symptomatic remission is achieved with initial therapy, the decision to undergo a trial of step-down management and discontinuation of therapy should be individualized. The choice of approach should take into consideration such factors as the patient's clinical status, the presence or likelihood of complications, the patient's previous response to treatment, the likelihood of follow-up (to monitor patients after therapy is stepped down or discontinued), and overall costs.

Refer to the original guideline document for further discussion of comparative studies and economic considerations.

In summary, there is currently no definitive evidence to support a particular approach in the maintenance therapy of Department of Defense (DoD) or Veteran Administration (VA) patients with uninvestigated GERD. PPIs are superior to H_2RAs , and a no-step PPI approach may be superior to a stepdown or no-step H_2RA approach for maintenance therapy in a population of patients. This guideline prefers a step-down approach, as it may individualize therapy to find the least acid-suppressive and least costly therapy needed for each patient. There has been no evidence of significant changes in quality of life or disease severity 6 months after initiating step-down management.

Intervention	Reference(s)		OQ	SR
If a patient responds to initial therapy,	GERD guideline expert	Ш	Ш	C
either step down then discontinue	opinion			
therapy (preferred) or continue current				
medication regimen				
Individualize decisions to undergo a trial	GERD guideline expert	Ш	Ш	С
of step-down management and	opinion			
discontinuation of therapy				
Patients who require continuous, long-	"An evidence-based	Ш;	Ш	С
term maintenance therapy should be	appraisal," 1999;	Ш		
referred for further diagnostic testing	DeVault & Castell, 1999			

M. Discontinue Therapy First or Step Down Then Discontinue Therapy

Objective

To discuss two methods of stepping down therapy in patients who have achieved symptomatic remission

- 1. Attempt treatment discontinuation first
- 2. Attempt treatment discontinuation after step-wise reduction in treatment intensity

Annotation

There is no standardized method for stepping down therapy, and no consensus on the optimal duration of initial therapy before attempting to step down therapy once symptoms are controlled. In efficacy trials, the duration of initial therapy is generally at least 4 to 8 weeks. Reports outlining protocols for step-down management or documenting the merits of step-down therapy in primary care patients are limited. There is also a lack of studies comparing patient outcomes resulting from different approaches to step-down management.

One reason for discontinuing therapy first is to determine early on which patients require any maintenance therapy. A step-down approach (discontinuation of PPI therapy or halving the PPI dose if tablet size made it possible, and reinstituting therapy upon relapse) has been associated with no significant changes in health-related quality of life measurements or disease severity at 6 months compared with baseline, despite a high relapse rate (85%). Discontinuing therapy first is consistent with the recommendations by Dent et al., who additionally recommend endoscopy if patients with uninvestigated GERD experience a relapse after stopping therapy (reinstitution of therapy before endoscopy is not specifically suggested). While discontinuation of medication after successful initial therapy can evaluate whether long-term treatment is necessary, this strategy could not be routinely recommended by Dent et al. because of conflicting data on the relapse rates of patients after stopping therapy. Unlike the guideline proposed by Dent et al., this guideline suggests reinstituting treatment upon relapse to provide symptomatic therapy while the patient is awaiting further evaluation.

Reducing treatment intensity in a step-wise fashion before discontinuation reveals the specific type of drug the patient requires for maintenance therapy (i.e., patients who relapse after stepping down to H_2RA therapy are those who require PPI therapy) before determining which patients require any maintenance therapy. Referral for further diagnostic testing should be considered for all patients who relapse or require continuous, long-term maintenance therapy. The two methods of stepping down therapy are modeled after the protocol used in U.S. veterans by Inadomi et al., where relapse within the first 2 weeks of discontinuation or halving the dose of PPI (if tablet size made it possible) was managed by reinstituting initial effective PPI therapy, and relapse after 2 weeks was treated by stepping up drug therapy (to double-dose H_2RA , prokinetics, or a combination of both). The 2-week period was chosen arbitrarily.

Both methods suggested by this guideline recommend restarting the initial drug regimen that was effective if patients relapse within 2 weeks of discontinuing or stepping down therapy. For relapses occurring after the first 2 weeks, this guideline suggests stepping up drug therapy.

There are important differences between the approach described here and the approach by Inadomi et al. One difference is the recommendation to use standard-dose H_2RA instead of double-dose H_2RA or prokinetics. Double doses of H_2RA are not recommended because of limited additional benefit gained over standard doses (see Annotation H). Prokinetics are not recommended because of the market withdrawal of cisapride and limited evidence to support the use of other prokinetics (see Prokinetic Agents, page 43 in the original guideline document). Another key difference is the suggestion to refer the patient for further diagnostic testing if relapse occurs, whereas the protocol used by Inadomi et al. was entirely based on symptoms. There is a lack of evidence that outcomes differ between symptom-based and endoscopy-based treatment of relapse. The provider should be aware that the specific methods suggested by this guideline have not been evaluated.

Both methods also use a step-wise decrease or increase in the degree of acid suppression based on a hierarchy of drug efficacy. For both NERD and erosive esophagitis, there is a hierarchy of efficacy for antireflux agents (from double-dose PPI down to standard-dose H_2RA). A similar hierarchy (from double-dose PPI down to antacids) for primary care practice has been suggested by Dent et al. (see Figure 1 in the original guideline document).

NOTE: Relapse on standard-dose PPI maintenance therapy and need for continuous long-term therapy are indications for further diagnostic evaluation. In this regard, the decision to use PPIs in either double or half doses for maintenance therapy should be made following diagnostic testing. There is evidence to support the use of half-dose PPI over standard-dose H₂RA maintenance therapy in a mixed population of patients with NERD or mild erosive esophagitis; but there is a lack of evidence in patients with uninvestigated GERD. The decision to use half-dose PPI therapy should be made after considering that half doses are currently possible only with lansoprazole suspension, omeprazole suspension, and pantoprazole tablets. (Also see the section Proton Pump Inhibitors in the original guideline document.)

The evidence supporting the use of antacids as maintenance therapy is limited. (See discussion of trials in the original guideline document.)

There is a remarkable lack of data on the long-term use of on-demand H₂RA maintenance therapy. (See original guideline document for discussion.)

The approach to maintenance therapy in patients who have been referred for further diagnostic testing (for example, because of alarm symptoms, extraesophageal symptoms, long duration of symptoms, relapse on medication, or need for continued, long-term maintenance therapy) should be based on diagnostic test results.

Intervention	Reference(s)	QE	OQ	SR
For stepping down maintenance	Inadomi et al., 2001;	11-3;	Ш	I
therapy, either discontinue therapy	GERD guideline expert	Ш		
first or discontinue treatment after a	opinion			
step-wise reduction in treatment				
intensity				
Refer patients who relapse or require		111;	Ш	C
continuous, long-term maintenance		111		
therapy for further diagnostic testing				
Refer patients for consultation before		111	111	C
considering the use of half-dose PPIs	opinion			
(only shown to be effective in				
patients with NERD or mild erosive				
esophagitis)				
Antacids for maintenance therapy	Lieberman, 1987; Behar et		11	C
	, , , ,	II-2;		
	"An evidence-based	II-3;		
	appraisal," 1999	111		
Half-dose H₂RA for maintenance	Kaul et al., 1986; Koelz et	I; I	ш	D
therapy (no different from placebo)	al., 1986			

Definitions:

Quality of Evidence

- I: Evidence obtained from at least one properly randomized controlled trial
- II-1: Evidence obtained from well-designed controlled trails without randomization
- II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
- III: Opinion of respected authorities, based on clnical experience, descriptive studies and case reports, or reports of expert committees

Overall Quality

- I (Good): High-grade evidence (I or II-1) directly linked to health outcome.
- II (Fair): High-grade evidence (I or II-1) linked to intermediate outcome; OR moderate-grade evidence (II-2 or II-3) directly linked to health outcome
- III (Poor): Level III evidence or no linkage of evidence to health outcome
- IV: Insufficient evidence

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, OR
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, OR
- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative impact on a frequent condition with a substantial burden of suffering, OR
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, OR
- No relative impact on either a frequent condition with a substantial burden of suffering, OR
- An infrequent condition with a significant impact on the individual patient level

Grade for Strength of Recommendation (SR)

Overall Quality of	Net Benefit of the Intervention			tervention
Evidence	Substantial	Moderate	Small	Zero or Negative
I	А	В	С	D
11	В	В	С	D
Ш	С	С	С	D
IV	I	I	I	D

Key:

- A A strong recommendation that the intervention is always indicated and acceptable
- B A recommendation that the intervention may be useful/effective
- C A recommendation that the intervention may be considered

- D A recommendation that a procedure may be considered not useful/effective, or may be harmful
- I Insufficient evidence to recommend for or against the clinician will use clinical judgment

CLINICAL ALGORITHM(S)

Clinical algorithms are provided in the original guideline document for:

- Initial Therapy of Gastroesophageal Reflux Disease (GERD)
- Maintenance Therapy of Gastroesophageal Reflux Disease (GERD)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected interventions.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of gastroesophageal reflux disease (GERD)

The desired outcomes of successful implementation of this guideline are to reverse impairment in the patient's health-related quality of life and prevent GERD-associated morbidity and mortality. These goals are achieved through the following key points:

- Identify and refer patients who require further evaluation or may need long-term follow-up by an appropriate specialist.
- Develop a plan for empiric initial therapy to relieve symptoms and promote esophageal healing.
- Optimize drug therapy to control symptoms if initial therapy did not provide adequate symptomatic relief.
- Develop a plan for maintenance drug therapy to prevent relapse and keep symptoms under control.
- Minimize complications due to GERD.

POTENTI AL HARMS

Side effects and drug interactions of medications are described in the original guideline document. In general, proton pump inhibitors (PPIs) and histamine 26 of 31

 $\rm H_2$ receptor blockers ($\rm H_2RA$) are well tolerated. The most frequently reported side effects of PPIs are diarrhea, nausea, abdominal pain, and headache. For $\rm H_2RAs$, side effects include headache, dizziness, diarrhea, constipation, mental status changes, and increases in liver enzymes. Gynecomastia has occurred in up to 1% of patients taking cimetidine for a month or longer.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technologic advances and patterns evolve. The ultimate judgment regarding a particular clinical procedure or treatment course must be made by the individual provider in light of the patient's clinical presentation, patient preferences, and the available diagnostic and treatment options. This guideline can assist providers in the care of an individual patient, but the use of a clinical practice guideline must always be considered as a recommendation within the context of a provider's clinical judgment.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Explicit indicators to measure implementation system wide are a part of the Veterans Health Administration's (VHA's) performance measurement system and are described in the Technical Manual on the Department of Veterans Affairs (VA's) Web site.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for management of adults with gastroesophageal reflux disease in primary care practice. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Mar 12. 65 p. [255 references]

ADAPTATION

The original guidelines that were merged in the creation of this document were (1) The Pharmacologic Management of Gastroesophageal Reflux Disease (PBM-MAP Publication No. 98-0010, dated September 1998, last updated March 2000) and (2) a draft update (last modified 20 January 2001) of Improving the Clinical and Economic Outcomes of Gastroesophageal Reflux Disease (GERD) (PEC Update, Vol. 98, Issue 4).

Updates of the present guideline relied primarily on two evidence-based publications on the diagnosis and management of gastrointestinal reflux disease (GERD), one developed by the American College of Gastroenterology and revised in June 1999, and the other prepared by an international panel of experts participating in the Genval Workshop and updated (with focus on primary care practice) in 2001.

DATE RELEASED

2003 Mar 12

GUIDELINE DEVELOPER(S)

Department of Defense - Federal Government Agency [U.S.] Department of Veterans Affairs - Federal Government Agency [U.S.] Veterans Health Administration - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Pharmacy Benefits Management (PBM) Strategic Healthcare Group (SHG): John E. Ogden, RPh, MS, FASHP, Chief Consultant, PBM; Virginia S. Torrise, PharmD, Deputy Chief Consultant, PBM; Michael Valentino, RPh, MHSA, Associate Chief Consultant, PBM; Joseph J. Canzolino, RPh, Assistant Chief

Consultant, PBM; Fran Cunningham, PharmD, Program Manager, Pharmacoepidemiologic and Outcomes Research; Muriel Burk, PharmD, Clinical Pharmacy Specialist; Elaine M. Furmaga, PharmD, Clinical Pharmacy Specialist; Mark Geraci, PharmD, BCOP, Clinical Pharmacy Specialist; Lori Golterman, PharmD, Clinical Pharmacy Specialist; Francine Goodman, PharmD, BCPS, Clinical Pharmacy Specialist; Cathy Kelley, PharmD, Clinical Pharmacy Specialist; Deborah Khachikian, PharmD, Clinical Pharmacy Specialist; Kathy Tortorice, PharmD, BCPS, Clinical Pharmacy Specialist

Medical Advisory Panel (MAP) for the Pharmacy Benefits Management Strategic Healthcare Group: Thomas Craig, MD, Chief Quality and Performance Officer, Office of Quality and Performance Management, Dept. of Veterans Affairs, Washington, DC; Thomas Dickinson, MD, Local Service Line Manager, Ambulatory Care Service Line, Brockton VAMC; Gregory Dalack, MD, Chief, Psychiatry Service, VA Ann Arbor Healthcare System, Assistant Professor of Psychiatry, University of Michigan; COL John Downs, MD, Medical Corps, U.S. Air Force, Program Director, Internal Medicine Residency, Wilford Hall Medical Center, Lackland AFB, Texas: Michael Ganz, MD, Chief, Nephrology, Cleveland VAMC, Associate Professor of Medicine, Case Western Reserve University; Peter A. Glassman, MBBS, MSc, Staff Internist, Department of Medicine, VAMC West Los Angeles, Assistant Professor of Medicine, University of California, Los Angeles; Matt Goetz, MD, Chief, Infectious Diseases, VA Greater Los Angeles Healthcare System, West Los Angeles VAMC; C.B. Good, MD, MPH, Chairman, Medical Advisory Panel, Staff Physician, Department of Medicine, Pittsburgh VAMC, Associate Professor of Medicine, University of Pittsburgh; Robert C. Goodhope, MD, Chief Medical Officer VA Outpatient Clinic, Tallahassee, FL; Robert Hariman, MD, Director, Cardiac Electrophysiology, Hines VA Hospital, Associate Professor of Medicine, Loyola University School of Medicine; Donald Holleman, MD, Director, Primary Care, Lexington VAMC, Associate Professor of Medicine, University of Kentucky; William Korchik, MD, Director, Extended Care Center, Medical Director, Adult Day Health Care, Minneapolis VAMC, Assistant Professor of Medicine, University of Minnesota; John Pope, MD, Director, Mental Health, Colmery-O'Neil VAMC, Instructor of Psychopharmacology, Karl Menninger School of Psychiatry; Alexander Shepherd, MD, Professor of Medicine and Pharmacology, University of Texas Health Science Center, San Antonio, TX

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Department of Veterans Affairs Web site.

Print copies: Available from the Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guideline for guidelines. Draft. Washington (DC): Veterans Health Administration, Department of Veterans Affairs. Available at: VHA Web site.
- Putting clinical practice guidelines to work in the Department of Veterans Affairs Veterans Health Administration. A guide for action. Washington (DC): Veterans Health Administration, Department of Veterans Affairs. Available at: <u>VHA Web site</u>.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 9, 2005.

COPYRIGHT STATEMENT

No copyright restrictions apply.

© 1998-2005 National Guideline Clearinghouse

Date Modified: 5/2/2005



